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Efficacy of Platelet-Rich Plasma for Chronic Lateral Ankle Instability After Modified Broström-Gould surgery: A Randomized, Single-Blinded, Prospective Controlled Trial

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Abstract

Background: Modified Broström-Gould (MBG) surgery is frequently used for chronic lateral ankle instability (CLAI). However, conventional postoperative management (CPOM) due to prolonged immobilization may have adverse effects on tendons, ligaments, and joints, causing stiffness. This prospective, randomized controlled trial aimed to determine outcomes among patients randomized to receive CPOM plus ultrasonography-guided triple injections of leukocyte-rich platelet-rich plasma (LR-PRP) compared to patients who receive only CPOM after MBG surgery.

Methods: The present study included 40 patients with symptomatic CLAI who were candidates for the MBG surgery. The patients were randomized into 2 groups of 20, the control and PRP groups. In the PRP group, patients were injected with 3 doses of LR-PRP solution using ultrasonographic guidance. In the first injection, 2 mL of LR-PRP was injected near the injury site, and in the second and third injections, 4 mL of LR-PRP was injected in the tibiotalar joint. All patients received a short leg splint for 2 weeks, followed by 4 weeks in a walking boot. The primary outcome measure was the visual analog scale (VAS), and the secondary outcome measures were the American Orthopaedic Foot & Ankle Society (AOFAS) ankle-hindfoot scale and ankle total range of motion (total ROM). The assessment was performed at baseline and 3 and 6 months after surgery.

Results: The mean VAS and AOFAS scores improved significantly in both groups 6 months after surgery ($P < .001$). However, the PRP group did not significantly improve in VAS or AOFAS scores compared with the control group. No clinically significant difference was observed between the 2 groups regarding the total ROM scores at month 3.

Conclusion: The application of LR-PRP after MBG surgery did not show any superior clinical or functional improvement over CPOM.

Level of Evidence: Level II, prospective randomized trial.

Keywords: platelet-rich plasma, ankle sprain, Broström-Gould, instability

Introduction

Lateral ankle sprains (LASs) are the most common ankle injuries that account for approximately 85% of ankle injuries and contribute to a considerable health care cost.[14,22] The lateral ligament complex includes the anterior talofibular ligament (ATFL), calcaneofibular ligament (CFL), and posterior talofibular ligament. The ATFL is the most frequently injured ligament, followed by the CFL and posterior talofibular ligament.[32] Most LASs can be managed successfully with conservative treatments, and functional

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rehabilitation. Even with adequate nonoperative treatments, up to 40% of LASs can lead to chronic lateral ankle instability (CLAI). If rehabilitation fails, surgical intervention is indicated to restore ankle function and structure.[11,24,32] The Modified Broström-Gould (MBG) procedure is the preferred operative treatment.[1,4,30] Conventional postoperative management (CPOM) varies among surgeons but generally consists of an initial 2- to 6-week period of the cast, splint, or boot immobilization and rehabilitative exercises after this initial period. Extended immobilization after postoperative protocols may have detrimental effects on muscles, tendons, ligaments, and joints, causing stiffness. Therefore, early mobilization can provide a more rapid return to daily or sports activities, remarkably so in the athlete population.[3,4,18,31]

In recent years, the interest in autologous biological treatments, particularly platelet-rich plasma (PRP), has increased significantly in orthopaedic surgery and sports medicine. PRP is a processed liquid fraction of autologous peripheral blood enriched with a platelet concentration above that typically contained in whole blood.[10] Besides platelets, PRP contains some inflammatory cells and large amounts of growth factors. Injection of PRP into or near the site of injury is thought to improve healing and tissue regeneration by promoting cell recruitment, proliferation, and angiogenesis by delivering growth factors and inflammatory cells. Numerous studies have focused on the efficacy of PRP in healing and reducing pain in soft tissue injuries. Some of these studies have shown the positive effect of PRP in reducing pain and function improvement in lateral elbow tendinosis and patellar tendinopathy. McRobb et al[23] conducted a systematic review on the effect of PRP on healing and clinical outcomes after anterior cruciate ligament reconstructive surgery and showed no consensus on the impact of PRP on pain, knee stability, and resultant knee function. Currently, there is scarcity of evidence supporting the use of PRP for treating musculoskeletal soft tissue injuries.[13,26] Also, we are unaware of any studies of PRP injection after MBG surgery for CLAI. Based on these controversial results and insufficient evidence, this prospective, randomized, controlled trial aimed to evaluate the clinical effect of triple injections of leukocyte-rich PRP (LR-PRP) after MBG surgery in patients with CLAI, measured with foot and ankle scales of function and pain.

Material and Methods

Study Design

We performed a prospective, single-center randomized controlled trial. The study was conducted at the Department of Orthopedics, Akhtar Hospital, Tehran, Iran, in 2022, by adhering to the principles of the Helsinki Declaration and after approval of the Ethics Committee of Shahid Beheshti University of Medical Sciences. The clinical trial was prospectively registered in the Iranian Registry of Clinical Trials (IRCT20200307046714N1). Written informed consent was obtained from each participant before enrollment in the study.

Participants

Patients with suspected CLAI were informed about the study by a trained senior orthopaedic resident in the clinic, and if interested, the orthopaedic resident called the main researcher. Detailed information about the study was given to the patients by telephone. An experienced foot and ankle surgeon evaluated the patients who were interested and appropriate for inclusion to verify the diagnosis of CLAI. Diagnosis of CLAI was based on the clinical history (a significant LAS that had not responded to appropriate conservative treatment, including pharmacologic treatment, a protective brace, and physical therapy, and associated with other symptoms such as recurrent sprains, pain, swelling, and restricted activity), clinical examination, and imaging studies. Clinical examination included the anterior drawer test and the talar tilt test to evaluate the ATFL and CFL. The findings were compared with the healthy side and complete tears of the ATFL with intact CFL and posterior talofibular ligament were also documented on magnetic resonance imaging (MRI). A diagnostic arthroscopy was also performed prior to the surgical reconstruction to reveal any intraarticular pathologies (osteochondral lesions, bony and soft tissue impingement, and loose bodies). Patients were eligible if they were aged $\geq$18 years with both a clinically diagnosed and MRI-diagnosed CLAI. Exclusion criteria were pregnancy, lactation, history of peripheral vascular diseases, rheumatoid arthritis, ankle osteoarthritis, ankylosing spondylitis, foot deformities, diabetes, intellectual disability, psychiatric disorders, prior surgery at the site of injury, bilateral ankle instability, osteochondral lesions, lesions of the tibiofibular syndesmosis, and those who did not give their consent to participate in the study.

Surgical Technique

All patients underwent the MBG surgery, performed by a single, well-experienced foot and ankle surgeon. A blinded foot and ankle surgeon collected patients' demographic profiles (sex, age, body mass index), and baseline VAS and AOFAS scores and total ROM before the surgery. The procedure was performed with the patient under a general anesthetic, in a supine position, with a bump under the ipsilateral hip, and with an inflated thigh tourniquet. A curvilinear incision was made over the anterior border of the lateral malleolus. The ATFL and the CFL were identified and exposed through blunt dissection. The ATFL footprint on the distal fibula was then exposed, drilled, and 2 intraosseous

suture anchors placed. A suture anchor was also placed in the CFL fibular footprint. The ATFL and the CFL were tightened with the ankle in neutral and slight eversion, and the posterior edge of the extensor retinaculum was opposed to the anterior edge of the fibula. The subcutaneous and skin were closed with Vicryl and nylon sutures, and a sterile dressing was placed. Operation and tourniquet time was also recorded for each patient.

CPOM

Postoperatively, a well-padded posterior short leg splint was applied to immobilize the ankle in the neutral dorsiflexion and slight eversion, and patients were kept nonweightbearing for 2 weeks. After 2 weeks, patients were put into a walking boot for 4 weeks and allowed fully weightbearing as tolerated immediately. Six weeks after surgery, the same physical therapy program was commenced for all patients under the supervision of a single physiotherapist, with the removal of the boot. Patients were then allowed to return to baseline activities approximately 12 weeks after surgery. Patients were visited in the clinic at 1 week, 2 weeks, 6 weeks, 3 months, and 6 months postoperatively.

Blinding and Randomization

Patients fulfilling the inclusion criteria were randomly allocated to the PRP group or the control group in a 1:1 ratio by an independent researcher not directly involved in the study. Randomization was performed using an online block randomization tool (www.sealedenvelope.com), with a variable block size of 2 or 4 and stratified based on age ($\geq$40 or $<$40 years). Neither the patients nor the radiologist performing the injections was blinded to the randomization. However, the outcome assessment was done by a foot and ankle surgeon unaware of patients' randomization. The physiotherapist prescribing the physical therapy program and researchers who performed statistical analyses were blinded to the randomization.

PRP Preparation

A senior orthopaedic resident prepared LR-PRP injections for the intervention group using the Rooyagen kit made by Arya Mabna Tashkis Corporation. For 2 mL of LR-PRP, 20 mL of whole blood was initially drawn from the patient's antecubital vein of the upper limb using an 18-gauge needle. Two milliliters of ACD-A was then added to the sample as an anticoagulant and passed through 2 steps of centrifugation; first at 1600 rpm for 10 minutes to isolate the erythrocytes and then at 3500 rpm for 6 minutes in order to concentrate the platelets. LR-PRP quantification was then performed to confirm that the platelet concentration had reached 5 ± 1 times that of the whole blood. Eventually, the first injection included 2 mL of LR-PRP. The preparation of the second and third injections was the same as the first injection, but for preparing 4 mL of LR-PRP, 40 mL of whole blood was taken from the patient instead of 20 mL. Four milliliters of ACD-A was then added to the sample as an anticoagulant and passed 2 steps of centrifugation similar to the first injection. Finally, the second and third injections included 4 mL of LR-PRP. Local anesthesia (lidocaine) was not added to the infusion because both lidocaine and PRP potentially affect the inflammatory cascade and may interact with and reduce the efficacy of PRP.[6,12]

Ultrasonography-Guided Injections

In administering the LR-PRP, ultrasonography was performed by an experienced radiologist using a high-frequency 5- to 12-MHz linear transducer (Hitachi Aloka Medical Systems, Tokyo, Japan). The first injection was given 1 week after surgery, and the second and third injections were given 2 and 6 weeks after surgery. The injections were done through the anterolateral approach while the patients were lying supine. After prepping the skin with antiseptic, while the ultrasound transducer was covered with a sterile barrier and using a sterile gel, a 21-gauge needle was inserted under real-time ultrasonographic guidance. In the first injection, 2 mL of the LR-PRP was injected adjacent to the ATFL and the CFL sutures. In the second and third injections, the needle was placed just lateral to the peroneus tertius tendon, medial to the lateral malleolus, and at the level of the ankle joint line, 4 mL of the LR-PRP was injected in the tibiotalar joint. A sterile dressing was placed after injections, and all patients were observed for possible bleeding 10-15 minutes after injections. After the first injection, the leg splint was applied again. Patients were instructed to avoid anti-inflammatory drugs such as NSAIDs, steroids, or drugs that affect platelets, from 24 hours before injections to 5 days after injections, but allowed to use maximum daily dose of 4 g acetaminophen.

Sample Size Calculation

A power analysis using G* power free software (version 3.1) determined the total number of cases at 38 (18 in each group) based on a power of 0.80 with a significance level of .05 and a β risk of 0.2 (2-sided; effect size = 0.93).[3,19,28] We planned to include 20 patients in each group to strengthen the data and account for a loss of follow-up.

Outcome Measurements

One experienced foot and ankle surgeon blinded to the patients' randomization conducted all the measurements in all patients of both groups. The primary outcome was to compare pain scores by visual analog scale (VAS)[17] at

baseline and 3 and 6 months after surgery in the 2 groups. The secondary outcomes included the Persian version of the American Orthopaedic Foot & Ankle Society (AOFAS)[29] ankle-hindfoot scale score at baseline and 3 and 6 months after surgery, and the ankle total range of motion (total ROM) at baseline and 3 months after surgery. A 35-cm universal plastic goniometer (Saehan, South Korea) was used to measure the total ROM. The terminology and techniques of measurements were those suggested by Norkin and White.[27] Eventually, all the plantarflexion, dorsiflexion, eversion, and inversion scores were added together and documented as ankle total ROM.

Statistical Analysis

All calculations were performed by using IBM SPSS Statistics, version 22. The continuous data were tested for normality. Demographic data were analyzed using the Student *t* test for normally distributed data, the Mann-Whitney *U* test for nonparametric data, and the χ^2 test for categorical data. The repeated measures analysis of variance with the Bonferroni post hoc test was performed for the data in each study group at various periods. The Student *t* test was used to compare the differences in outcomes between the groups. All statistical tests were 2-tailed, and all results were presented with a 95% CI. The significance level was $P \leq .05$.

Results

In this clinical trial, 55 patients were screened; of these, 9 patients did not meet the inclusion criteria, and 6 patients declined participation. Accordingly, 40 patients were enrolled in the study and randomized to the PRP group (n = 20) or the control group (n = 20) (Figure 1). The baseline demographic and clinical characteristics of participants are summarized in Table 1, and there were no significant differences in the variables between the 2 groups. Table 2 shows the VAS scores, AOFAS scores, and total ROM scores before and after surgery. Comparing the baseline data, a significant improvement in VAS and AOFAS scores was observed in the PRP and control groups 3 and 6 months after surgery ($P < .001$). Comparing the 2 groups, no statistically significant difference was found between mean differences in the VAS scores and AOFAS scores from baseline after 3 and 6 months (Table 3, Figure 2). No statistically significant difference was observed between the total ROM scores at baseline and month 3 in the PRP group. The total ROM scores in the control group declined significantly at month 3 compared to baseline ($P = .001$). Comparing the 2 groups, a significantly greater decrease in the total ROM scores was found in the control group after 3 months ($P = .030$) (Table 3). No patients experienced any side effects from the surgery or injections during the study.

Discussion

This randomized clinical trial showed no significant differences in terms of postoperative pain between CPOM and CPOM + triple injections of LR-PRP at 6 months of follow-up. A statistically significant improvement in the AOFAS and VAS scores were found in both groups ($P < .001$) (Table 2). Regardless of the treatment group, patients had a mean score of 93.70 on the AOFAS 6 months after surgery. These results are approximately similar to the results of a systematic review performed by Guelfi et al,[15] which included a total of 505 patients and revealed mean scores of 90.1 for the AOFAS in the open Brostrom procedure group. The VAS score indicated good results, and the overall average scores of the 2 groups and treatment groups were lower than those of a systematic review performed by Attia et al.[2] The total ROM scores in the control group declined significantly compared with the PRP group after 3 months ($P = .030$) (Tables 2 and 3). However, the difference was not clinically relevant (4.6 degrees). The minimal clinically important difference for the ankle ROM has not yet been determined after MBG surgery. However, some studies have documented ankle ROM differences before and after other ankle surgeries. Hsu et al[16] showed that ankle inversion decreased by approximately 14 degrees after the modified Brostrom-Evans procedure at an average 8-year follow-up. In a study by Cao et al,[5] patients with concurrent lateral ankle instability and osteochondral lesions of the talus showed a 12.4-degree increase in dynamic ankle plantarflexion plus dorsiflexion ROM. In the current study, the 4.6-degree difference in the total ROM is clinically irrelevant. However, this should be taken with caution because of the short follow-up period, particularly after 6 weeks of immobilization.

To our knowledge, this is the first randomized controlled trial investigating the use of triple injection of LR-PRP after MBG surgery. An important difference between the current study and previous studies is injecting LR-PRP in the tibiotalar joint in addition to the ligaments. However, several comparative studies have investigated the use of PRP in the nonoperative treatment of acute LASs. The present study's findings follow a double-blinded randomized controlled trial comparing the effect of 1 PRP injection vs 1 placebo injection on severe LAS in which PRP did not show benefit over placebo in either pain control or function 3, 8, and 30 days after injection.[28] A recent clinical study by Blanco-Rivera et al[3] evaluating the effect of a single PRP injection in patients with acute LAS treated with rigid immobilization reported no significant difference in either pain control or function 24 weeks after injection, although it showed pain relief and function improvement 8 weeks after injection. However, this study's results should be taken with caution because of the absence of a robust statistical analysis, and neither the patients nor the observers were blinded to

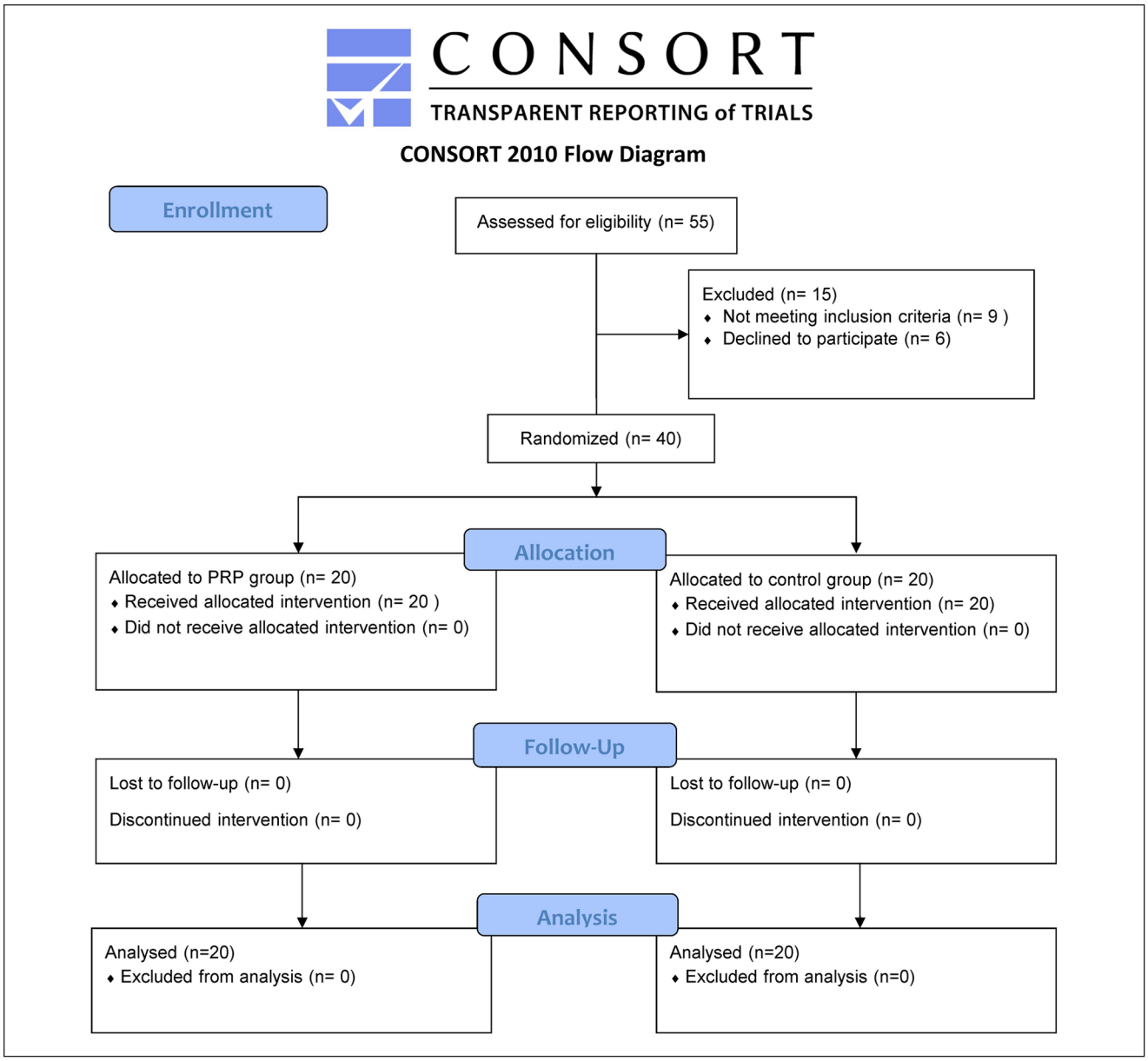

Figure 1. Study flow chart.[25]

the injections.[7] In contrast to our results, one randomized clinical trial in elite athletes with high ankle sprains showed a shorter return to play time, rapid stabilization of the syndesmosis joint, and less long-term residual pain after 2 injections of PRP compared with the rehabilitation program.[19] These difference in results could be because of differences in PRP preparation methods, the degree of LAS, interventions performed for patients, and follow-up periods. In the current study, the LR-PRP injection did not result in clinically significant differences in the VAS and AOFAS scores (Table 3).

Some previous studies have documented the positive results of PRP gels in reducing the incidence of arthrofibrosis in various orthopaedic surgical situations, particularly in knee arthroplasty.[8,9] Arthrofibrosis is defined as joint pain and stiffness that causes limitation of both active and passive ROM and is due to adhesions and contracture of the joint, particularly after a prolonged period of immobilization.[20,21] In the present study, there was no clinically significant difference in the total ROM scores between the 2 groups. However, the effect of LR-PRP in reducing arthrofibrosis incidence is not well investigated in the current study because of the short

Table 1. Baseline Demographic and Clinical Characteristics of Patients[a].

	PRP Group (n=20)	Control Group (n=20)	*P* Value
Age, y	34.45±11.72	39.00±10.97	.213[b]
Sex, male/female	13:17	9:11	.204[c]
Weight, kg	83.20±14.84	76.20±11.28	.101[b]
Height, cm	174.65±11.06	169.30±9.92	.116[b]
BMI	27.32±4.52	26.66±3.88	.623[b]
Operation time, min	83.75±3.19	83.75±3.93	.883[d]
Tourniquet time, min	72.00±2.99	73.00±4.10	.529[d]
VAS score	7.94±1.05	7.73±1.16	.563[b]
AOFAS score	67.35±10.42	65.40±9.59	.542[b]
Total ROM	108.75±9.80	107.75±10.82	.761[b]

Abbreviations: AOFAS, American Orthopaedic Foot & Ankle Society ankle-hindfoot score; BMI, body mass index; PRP, platelet-rich plasma; ROM, range of motion; VAS, visual analog scale.
[a]Data are shown as mean ± SD or n.
[b]Student *t* test.
[c]Pearson χ^2 test.
[d]Mann-Whitney *U* test.

Table 2. All the Outcome Measures in Each Group at Baseline and 3 and 6 Months After Surgery.

	PRP Group (n=20)		Control Group (n=20)	
	Mean±SD	*P* Value	Mean±SD	*P* Value
VAS				
Baseline	7.94±1.05		7.73±1.16	
Month 3	1.10±0.86	<.001[a]	0.89±0.79	<.001[a]
Month 6	0.95±0.88	<.001[a]	0.80±0.76	<.001[a]
AOFAS				
Baseline	67.35±10.42		65.40±9.59	
Month 3	94.35±3.66	<.001[a]	90.05±6.42	<.001[a]
Month 6	95.90±3.19	<.001[a]	91.50±5.42	<.001[a]
Total ROM				
Baseline	108.75±9.80		107.75±10.82	
Month 3	106.90±8.27	.161[a]	101.30±8.13	.001[a]

Abbreviations: AOFAS, American Orthopaedic Foot & Ankle Society ankle-hindfoot score; PRP, platelet-rich plasma; ROM, range of motion; VAS, visual analog scale.
[a]Paired *t* test.

follow-up period and utilized methodology. Finally, it is challenging to directly compare the current study's findings with those of the previous studies because variations in the PRP preparation methods, follow-up period, and severity of LAS may affect the results. However, the results of our study show that LR-PRP may not provide clinical improvement in terms of postoperative pain in patients with CLAI.

The present study had some limitations that need to be addressed. First, this study did not include placebo injections in the control group. Nevertheless, in the study by Rowden et al,[28] the patients in the control group received 1 injection of sterile normal saline as a placebo and reported no side effects of injection. However, triple non-PRP or shamed-controlled injections in the control group was unacceptable and unfeasible in our country because of the invasive procedure of injection. Hence, further prospective studies are encouraged with sham-controlled injections. Second, small sample size and short follow-up period caused limitations to the study. Third, PRP injections using different locations or timing could potentially result in different outcomes. Fourth, we did not measure the total ROM at the 6-month follow-up. Fifth, the ankle ROM measurements were not provided separately for each plane. Sixth, we did not compare the injured sides with the healthy sides. Seventh, a CLAS has a long recovery time; therefore, a longer follow-up would have been desirable to determine

Table 3. Changes of Outcome Measures From Baseline at 3 and 6 Months After Surgery in the PRP Group Compared With the Control Group[a].

	PRP Group (n=20)	Control Group (n=20)	*P* Value
VAS			
Baseline	Ref		
Month 3	−6.80±1.15	−6.85±1.63	.911[b]
Month 6	−7.05±1.23	−7.00±1.58	.912[b]
AOFAS			
Baseline	Ref		
Month 3	27.00±11.87	24.65±13.70	.566[b]
Month 6	28.55±11.41	26.10±12.52	.522[b]
Total ROM	Ref		
Month 3	−1.85±5.66	−6.45±7.17	.030[b]

Abbreviations: AOFAS, American Orthopaedic Foot & Ankle Society ankle-hindfoot score; PRP, platelet-rich plasma; ROM, range of motion; VAS, visual analog scale.
[a]Data are shown as mean ± SD.
[b]Student t test.

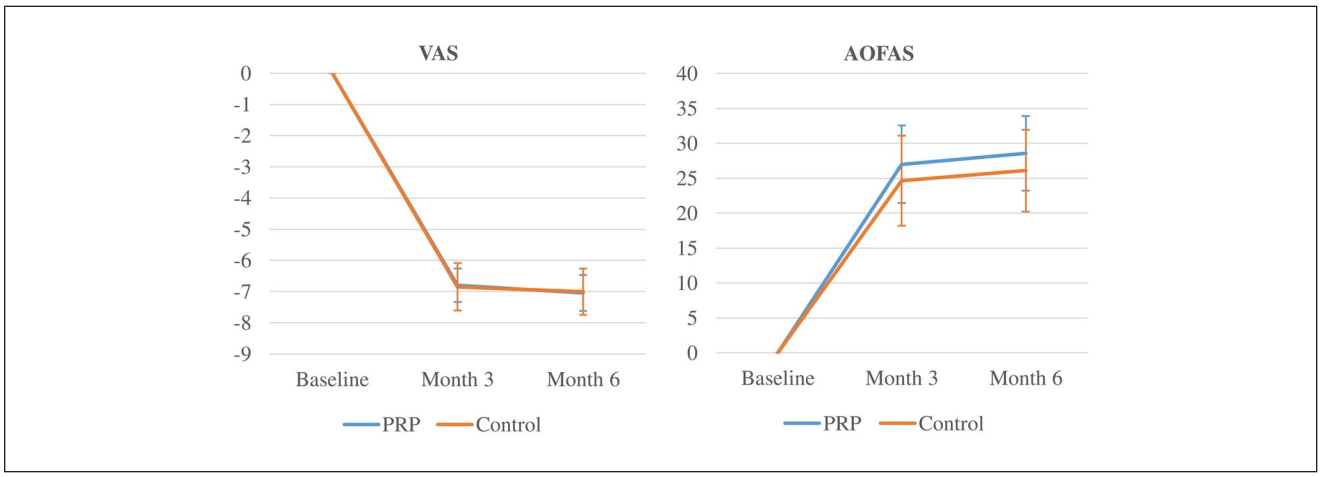

Figure 2. Mean change from baseline in the VAS and AOFAS scores in the PRP group compared with the control group. Comparing both groups, there was not a significant difference between mean changes in the VAS and AOFAS scores from baseline after 3 and 6 months. AOFAS, American Orthopaedic Foot & Ankle Society ankle-hindfoot score; PRP, platelet-rich plasma; VAS, visual analog scale.

whether there could have been a long-term LR-PRP effect. However, it is difficult to believe there should be a delayed LR-PRP effect when no effect was seen approximately 20 weeks after triple injections.

Conclusion

In summary, the ultrasonography-guided triple injection of LR-PRP+CPOM did not show clinically significant differences in terms of pain relief compared with CPOM at the 6-month follow-up. To conclude, the present study did not support the use of LR-PRP after MBG surgery for CLAS. A more extensive study, including shamed-controlled injections, would be required to confirm these results.

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Ethical Approval

Ethical approval for this study was obtained from the Ethics Committee of Shahid Beheshti University of Medical Sciences,

Tehran, Iran (IR.SBMU.RETECH.REC.1399.1264). The clinical trial was also prospectively registered in the Iranian Registry of Clinical Trials (IRCT20200307046714N1).

Declaration of Conflicting Interests

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